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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,079	09/04/2001	Atsushi Suzuki	213502US0	1164
22850	7590	05/17/2005	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			COE, SUSAN D	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/944,079	SUZUKI ET AL.	
	Examiner	Art Unit	
	Susan D. Coe	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-9 and 11-36 is/are pending in the application.
- 4a) Of the above claim(s) 15-18 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-9, 11-14, 19-29 and 32-36 is/are rejected.
- 7) ☒ Claim(s) 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendments filed February 14, 2005, November 15, 2004, and October 8, 2004 have been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 32-36 have been added.
3. Claims 6-9 and 11-36 are pending.

Election/Restrictions

4. In Paper No. 6, dated February 19, 2002, applicant elected with traverse Group II, claim 6, now including claims 7, 8, 9, and 11-36, chlorogenic acid for species A, and organic acid having a molecular weight of 60 to 300 for species B. Lactic acid was selected as the species examined for B. Based on the amendments to the claims, this species of lactic acid is now considered free of the art. Thus, an additional species was selected for examination. The selected species is ascorbic acid.
5. Claims 15-18 and 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, i.e. they do not specifically contain the elected species of ascorbic acid, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.
6. Claims 6-9, 11-14, 19-29, and 31-36 are examined on the merits in regards to the elected species.

Claim Objections

7. Claim 31 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claims 32 and 33 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. These claims depend from claim 6 which is drawn to a method of treating using a composition "consisting essentially of" components A and B. Claims 32 and 33 state that the composition "further comprises." This conflict in scope fails to further limit claims 32 and 33.

Claim Rejections - 35 USC § 112

9. Claims 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As discussed above, claims 32 and 33 cause a conflict in scope with the parent claim. Thus, the actual scope of the claims are unclear.

Claim Rejections - 35 USC § 103

10. Claims 6-9, 11-14, 19-29, and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (Chinese Pharm. Journal 91994), vol. 46, no. 6, pp. 575-582) and Duffy et al. (Lancet (1999), vol. 354, pp. 2048-9).

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Cheng teaches using isolated chlorogenic acid to treat hypertension (see Table 1).

Duffy teaches using ascorbic acid to treat hypertension.

These references show that it was well known in the art at the time of the invention to use chlorogenic acid and ascorbic acid to treat hypertension. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used to treat hypertension, an artisan of ordinary skill would have a reasonable expectation that a combination of the two substances would also be useful in treating hypertension. Therefore, the artisan would have been motivated to combine chlorogenic acid and ascorbic acid together to treat hypertension. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal

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amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

The references do not specifically teach formulating the composition in the forms claimed by applicant in claims 32-34. However, these forms are well known in the art as suitable formulations for pharmaceutical compositions. Thus, a person of ordinary skill in the art would reasonably be expected to formulate the composition taught by the combination of the references in these forms.

Double Patenting

11. Claims 6-9, 19-29 and 32-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-6, 10-16, and 30-39 of copending Application No. 09/922,694 for the reasons set forth in the previous Office action.

Since this is provisional rejection, applicant has requested that the rejection be held in abeyance until patentable subject matter is identified. This rejection is still considered valid until such time.

12. Claims 6-9, 19-29 and 32-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-16 of copending Application No. 10/632,810 or copending Application No. 10/826,289 for the reasons set forth in the previous Office action.

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Since this is provisional rejection, applicant has requested that the rejection be held in abeyance until patentable subject matter is identified. This rejection is still considered valid until such time.

13. Claims 6-9, 11-14, 19-29, and 32-36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-6, 10-16, and 30-39 of copending Application No. 09/922,694 in view of Duffy.

09/922,694 claims using chlorogenic acid to treat hypertension. However, the application does not specifically claim combining the chlorogenic acid with the elected species of ascorbic acid.

Duffy teaches using ascorbic acid to treat hypertension.

These references show that it was well known in the art at the time of the invention to use chlorogenic acid and an organic acid to treat hypertension. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used to treat hypertension, an artisan of ordinary skill would have a reasonable expectation that a combination of the two substances would also be useful in treating hypertension. Therefore, the artisan would have been motivated to combine chlorogenic acid and an organic acid together to treat

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hypertension. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

The references do not specifically teach using the ingredients in the amount claimed by applicant; however, as discussed above, this modification of ingredient amount is considered to be an obvious modification of parameters.

This is a provisional obviousness-type double patenting rejection.

14. Claims 6-9, 11-14, 19-29, and 32-36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-16 of copending Application No. 10/632,810 or copending Application No. 10/826,289 in view of Duffy

10/632,810 and 10/826,289 and claim using chlorogenic acid to treat hypertension. However, the application does not specifically claim combining the chlorogenic acid with the elected species of ascorbic acid.

Duffy teaches using ascorbic acid to treat hypertension.

These references show that it was well known in the art at the time of the invention to use chlorogenic acid and an organic acid to treat hypertension. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074,

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1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used to treat hypertension, an artisan of ordinary skill would have a reasonable expectation that a combination of the two substances would also be useful in treating hypertension. Therefore, the artisan would have been motivated to combine chlorogenic acid and an organic acid together to treat hypertension. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

The references do not specifically teach using the ingredients in the amount claimed by applicant; however, as discussed above, this modification of ingredient amount is considered to be an obvious modification of parameters.

This is a provisional obviousness-type double patenting rejection.

15. Claims 6-9, 11-14, 19-29, and 32-36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of copending Application No. 10/810,611 in view of Duffy.

10/810,611 claims using esters of chlorogenic acid to treat hypertension. However, the application does not specifically claim combining the chlorogenic acid with the elected species of ascorbic acid.

Duffy teaches using ascorbic acid to treat hypertension.

These references show that it was well known in the art at the time of the invention to use esters chlorogenic acid and an organic acid to treat hypertension. It is well known that it is prima

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facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used to treat hypertension, an artisan of ordinary skill would have a reasonable expectation that a combination of the two substances would also be useful in treating hypertension. Therefore, the artisan would have been motivated to combine esters of chlorogenic acid and an organic acid together to treat hypertension. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

The references do not specifically teach using the ingredients in the amount claimed by applicant; however, as discussed above, this modification of ingredient amount is considered to be an obvious modification of parameters.

This is a provisional obviousness-type double patenting rejection.

16. No claims are allowed. However, claim 31 would be allowable if amended to overcome the above claim objection.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.

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A handwritten signature in black ink, appearing to read "Susan D. Coe".

5-11-05

Susan D. Coe
Primary Examiner
Art Unit 1654